



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

MDOT/N

Telephone (973) 526-6008

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

WARNING LETTER

**Certified Mail
Return Receipt Requested**

File # 98-NWJ-38

September 22, 1998

Larry Freeborn
President
Tranquility Farms, Inc.
10 Tranquility Farms Lane
Andover, NJ 07821

Dear Mr. Freeborn:

An investigation at your dairy operation located in Andover, NJ, conducted by FDA Investigator Muralidhara B. Gavini on August 26, 1998 through September, 8, 1998, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii), 402(a)(4) and 402(a)(5) of the Federal Food, Drug and Cosmetic Act (the Act), and you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On May 19, 1998, you sold a bovine, identified as tag 5023, for slaughter as human food to [REDACTED]. That animal was then sold by [REDACTED] and transported to [REDACTED]. USDA analysis of tissue samples collected from the animal in question identified the presence of 0.38 ppm Gentamycin Sulfate. No tolerance for Gentamycin Sulfate has been established in the edible residues of bovines, per Title 21, Code of Federal Regulations, Part 556.300. The presence of Gentamycin Sulfate in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions inadequate to prevent diseased and / or medicated animals bearing potentially harmful drug residues from entering the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs that have been approved for use in those species. The Gentamycin Sulfate product you treated the animal in question with is not approved for use in bovines. Additionally, you did not withhold the animal in question from slaughter for a sufficient time to permit depletion of any potentially hazardous residue of Gentamycin Sulfate from edible tissues, as the instructions for use of the drug indicated. Finally, you did not maintain a system of medication and treatment records that, at a minimum, identify the treated animal, date(s) of

treatment, drug(s) administered, person(s) administering the drug(s), and the withdrawal time prior to slaughter.

Our investigation also showed you adulterated the drug Gencocyn (Gentamycin Sulfate) that you used to treat the animal in question within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved labeling. Your uses of the drug, both in a species for which it was not approved and without following the labeled withdrawal period, caused the drug to be unsafe for use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

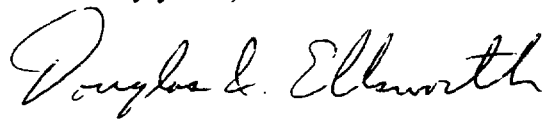
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

A handwritten signature in cursive script that reads "Douglas I. Ellsworth". The signature is written in dark ink and is positioned above the printed name and title.

Douglas I. Ellsworth
District Director